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June 26, 1997

Dr. Harold Varmus

Director

National Institutes of Health
Building 1, Room 126
Bethesda, Maryland 20892

SUBJECT: CellPro Petition to Exercise March-In Rights

Dear Dr. Varmus:

The Council on Governmental Relations (COGR) has serious concerns about CellPro's petition to exercise "march-in rights" under 35 USC 203 for several inventions that were patented by The Johns Hopkins University and subsequently licensed to Becton Dickinson and Baxter Healthcare.

The COGR membership consists of 141 research-intensive U.S. universities that participate in the transfer of technology from their laboratories to the private sector. Since its enactment in 1980, the Bayh-Dole Act has been very effective in providing a mechanism for universities to actively transfer technology to the private sector in a way that ensures that the public will benefit from new products and services. A critical feature of this process is the exclusive licensing of embryonic technologies to companies that are willing to take significant risks and make critical investments for the development and commercialization of such technologies. Exclusive licenses provide corporations with the necessary protection afforded by the U.S. patent laws and that, in turn, provides an important incentive to those corporations to invest in developing new technologies. Accordingly, COGR and its member universities are concerned about any action that would decrease the certainty that exclusive licensees require when they assume the economic risk of commercializing federally-funded inventions. Decreasing that certainty will undermine the extraordinarily positive societal benefits of the Bayh-Dole Act.

The exercise of "march-in rights" is permitted under 35 USC 203 when reasonable steps have not been taken to assure practical application of a federally-funded invention or to alleviate health or safety needs that are not reasonably satisfied by the licensee. COGR believes that the actions

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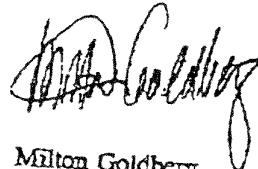
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taken by The Johns Hopkins University and its exclusive licensees have met this requirement. We also note that commitments have been made by Johns Hopkins University licensees to assure availability of the technology to the public and to all affected patients.

If NIH exercises its march-in rights to resolve a dispute of this nature, currently being addressed in the courts, the potential value of patent rights derived from federal funding and licensed to private industry could be significantly diminished. This, in turn, will lead to a critical reduction in the private sector's interest in licensing new university technology, thereby slowing or preventing the adoption of innovations important to the welfare of the general public.

Given our understanding of the available facts in this matter, COGR urges NIH to deny the petition from CellPro.

Sincerely,



Milton Goldberg